BQC - 92 – 053

Date: August 31, 1992

To: Hospitals HOSP 15
End Stage Renal Disease Facilities ESRD 5

From: Larry Tainter, Director
Bureau of Quality Assurance

Subject: Food and Drug Administration (FDA) Safety Alert

Attached is a copy of a recent FDA safety alert regarding aluminum and other trace element contamination in dialysis facilities.

Please disseminate this information. Additional copies may be obtained from Alvin Thomas of FDA at (301) 443-2436. If you have questions regarding the information, please contact Gwen Michel at (312) 886-5211 or Sally Jo Wieling at (312) 353-8853.

LT/SS/jh 4988a.nm

cc: -BQC Staff
-Office of Legal Counsel
-Ann Haney, DOH Admin.
-Kevin Piper, BHCF Dir.
-HCFA, Region V
-Illinois State Agency
-Ohio State Agency
-Michigan State Agency
-Indiana State Agency
-Minnesota State Agency
-WI Coalition for Advocacy
-Service Employees Intern. Union
-WI Counties Assn.
-WI Medical Recds Assn. Cons. Comm.
-WI Assn. of Hospital SW and Discharge Planners
-WI Assn. of Medical Directors
-Admin., Division of Care and Treatment Facilities
-Non-LTC BQC Memo Subscribers
-WI Hospital Association

Department of Health & Human Services
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July 1992

Refer to: CR2

Division of Health Standards and Quality Regional Program Letter No. 92-28

Subject: FDA Safety Alert: Aluminum and Other Trace Element Contamination in Dialysis Facilities

Attached for your information is an FDA Safety Alert. We have been advised that the alert has been sent to all hemodialysis personnel and water or dialysis services contractors. The alert warns of a potentially hazardous situation when dialysis patients are exposed to dialysate with excessive aluminum levels.

Although the information in the safety alert does not directly relate to the Conditions for Coverage/ Participation of any of the facilities we regulate, your office should be aware of any potential risks to patients and staff due to poor professional practices or unsafe medical devices.

Please take whatever action you believe necessary to inform those under your jurisdiction about this problem. Anyone wishing additional copies of the alert should contact Mr. Alvin Thomas at the FDA. His phone number is (301) 443-2436.

If you have any questions regarding this matter, please contact Gwen Michel at (312) 886-5211 or Sally Jo Wieling at (312) 353-8853, on my staff. Thank you for your attention to this serious matter.

/s/ Charles Bennett
Branch Chief
Survey and Certification Review Branch
Division of Health Standards and Quality

Enclosures

Department of Health & Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

FDA SAFETY ALERT:
Aluminum and Other Trace Element Contamination in Dialysis Facilities

TO: HEMODIALYSIS PERSONNEL **MAY 20, 1992**
WATER OR DIALYSATE SERVICE CONTRACTORS

This is to alert you to a potentially hazardous situation in which dialysis patients have been exposed to dialysate with excessive aluminum levels. These high levels were leached over time from components of the dialysate delivery system. Other trace elements (e.g., iron, copper) could also leach out and contaminate the dialysate in certain circumstances. **Please share this Alert with those in your organization who are responsible for water treatment, dialysate delivery system and patient care.**

In a recent incident at a large suburban dialysis facility, investigated by the Food and Drug Administration and the Centers for Disease Control (CDC), a large number of patients were found to have elevated serum aluminum levels. **Three patient deaths** were association with aluminum toxicity.

Preliminary findings indicate that the acidified portion of bicarbonate-based dialysate solution was stored and/or metered to the dialysis patients' proportioning hemodialysis system through an aluminum-containing pump. Aluminum from the pump had leached unexpectedly into the dialysate concentrate during transfer to the patient.

To eliminate the risk of trace element contamination, it is recommended that each dialysis facility reassess its entire dialysate delivery system, including concentrate delivery transfer and storage devices. The compatibility of the various components used for the preparation and delivery of a safe dialysate should be determined.

A reassessment of the water and dialysate systems is particularly important because, according to a recent CDC survey (1), more than 72% of reporting dialysis facilities are now using bicarbonate-based dialysate. In addition, many facilities have adapted their existing physical plants from acetate to bicarbonate without full consideration of the effect of lower pH on the dialysate concentrate delivery system. The corrosive effects of low pH (<5.5) solutions, such as the acidified portion of bicarbonate dialysate, increases the amount of leaching of any metals used in components of the dialysate delivery system.

Elevations in the serum aluminum levels in the dialysis patient population have typically been attributed to improper water treatment, use of phosphate binders, and the dialysis equipment. Aluminum and other trace elements can cross the dialyzer's semi-permeable membrane, be taken up by the blood and be deposited in the patient's body. The deposition of aluminum has caused anemia, bone manifestations, and transient or permanent neurological symptoms including encephalopathy (i.e., dialysis dementia), and death (2).

The following precautions are recommended:

1. **Reassess the design of and the components used in the water treatment, concentrate delivery transfer/storage, and dialysate delivery system whenever changing or updating any component of an existing dialysis unit.** The assessment should include evaluating the

compatibility of all components within the fluid pathway used to transport water and dialysate concentrate or prepared dialysate to the patients' dialyzer. It should be determined that there is no risk to the hemodialysis patient from the leaching of trace elements from the components in the fluid pathway used for the dialysate delivery system (3,4).

2. Routinely monitor all dialysis patients' blood chemistries for serum aluminum levels. Be advised that these serum levels may not necessarily reflect the actual total body burden of aluminum. When elevated serum aluminum levels are observed, dialysis personnel should initiate appropriate corrective actions, such as avoiding the use of aluminum-based phosphate binders, and beginning chelation therapy.

Sincerely yours,

/s/ James S. Benson
Director
Center for Devices and Radiological Health

1. Alter, MJ, Favero MS, Moyer, LA, and Bland, LA. National Surveillance of Dialysis-associated Diseases in the United States, 1989. ASATO Transactions, 37(2) p. 97-109, April-June, 1991.

2. Luehmann, DA, Keshaviah, PR, Ward, RA, Klein, E and Thomas, AW. A Manual on Water Treatment for Hemodialysis. FDA 89-4234. HHS, Rockville, MD, 1989.

3. Association for the Advancement of Medical Instrumentation. American National Standard for Hemodialysis Systems (AAMI: RD-5-1981) Arlington, VA (1982).

4. Vlcheck, DL, Burrows-Hudson, S, and Pressly, N. Quality Assurance Guidelines for Hemodialysis Devices. FDA 91-4161. HHS, Rockville, MD, 1991.